IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs.

No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Defendant.

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REPORTER'S TRANSCRIPT OF PROCEEDINGS

FINAL PRETRIAL CONFERENCE

MONDAY, OCTOBER 1, 2018, 10:00 A.M.

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(Appearances continued next page...)

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                        HUNTINGTON, WEST VIRGINIA
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                    MONDAY, OCTOBER 1, 2018, 9:51 A.M.
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              THE COURT: Good morning.
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              MR. CHILDERS: Good morning, Your Honor.
              MS. JONES: Good morning, Your Honor.
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              THE COURT: We'll go off the record. I understand the
      the parties wanted to bring a matter to the Court's attention.
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          (Off-the-record discussion.)
              MR. CHILDERS: Sorry. The first person would be
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      Melissa Ann Mobley, M-O-B-L-E-Y. Second is Victoria Lewis
      Pickavance, P-I-C-K-A-V-A-N-C-E. And the third is Linda Marie
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      Watts, W-A-T-T-S.
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              Thank you, Your Honor.
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              THE COURT: Thank you.
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              MR. LEWIS: Thank you.
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              THE COURT: All right. Are we otherwise ready to
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     proceed?
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              MR. CHILDERS: Yes, sir.
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              THE COURT: Great.
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              So here's what I'd like to sort of list as the
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      schedule of the agenda. First I want to hear brief argument
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      and then hopefully rule upon the defendant's motion to
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      preclude certain evidence. Then I want to turn to the
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      deposition issues, first plaintiffs' objections to the
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defendant's deposition designations, then the defendant's objections to plaintiffs'.

After that, I want to go through the proposed voir dire and preliminary instructions. Following that, if there is anything else that needs to be addressed from the joint pretrial order, I want to hear about that.

And then the last matter, I have a few relatively minor matters a few minor matters that I want to discuss with you just about logistics, in particular a couple of matters that my court reporter asked that I raise and clarify with the parties.

So let's start, then, with the defendant's motion to preclude evidence. I've read all this, I've got a pretty good understanding, but I want to give the parties a chance for some brief argument. Go ahead.

MR. LEWIS: Should I do it from here, Your Honor, or do you want me --

THE COURT: You can do it from there if you're comfortable. Just make sure you use that microphone so my court reporter can hear it well.

MR. LEWIS: Very good. Thank you, Your Honor, for considering the motion.

You know, it's really -- I was trying to think of a good analogy on the defense side to really describe what we are moving for because I think there is some confusion based

on the papers that I've seen from plaintiffs about what we're really asking for.

And so as a defendant, let's assume that the plaintiffs never requested our complaint database at all, just for whatever reason in discovery. And we did get to the trial, and as defendants, we seek to argue in front of the jury that there are no complaints associated with this product. Now just because the plaintiffs have not asked for our complaint database doesn't mean I get to argue a fact that isn't true to the jury or that I can't confirm it's true. That's not appropriate.

And if there indeed were complaints about a product, or in fact I didn't even know if there were or not, I still can't argue to the jury there are no complaints associated with that product. I could say, based on what we've collected, or based on the evidence you will hear, there are no complaints associated with that product, but there is a back story there. And there is a big difference between saying it as a fact and saying that, hey, based on the homework we've done, we don't have that evidence.

And that's really what we are seeking here with respect to the plaintiffs' use of the warfarin medication. We don't have all of the medical records from the entire time frame that Betty Knight was on warfarin, we just don't. Should the plaintiffs have collected those and produced those

to us? Maybe, but let's put that aside for a second. Could we have done it? Maybe, but let's put that aside.

We know for a fact that we can't really represent to the jury that in fact Betty Knight had no bleeds with warfarin during the entire time that she had the medication. We can say based on the records we've collected, the plaintiffs can argue this, maybe, maybe there isn't any evidence. We think maybe there is, but we think the jury shouldn't be misled into thinking it's a fact that she did have a bleed while she was taking warfarin.

So either we need to preclude the plaintiffs from making that argument and stating that as fact or we need to be able to tell the jury the whole story. We didn't collect all of the information, so we don't know, we're not sure.

THE COURT: Well, as I understand it, the plaintiffs' evidence is, first, they have medical records which have been shared, and Dr. MacFarland's comes to mind most readily, where Dr. MacFarland purported as part of the history that there was prior GI bleeds on warfarin.

But then it seems that when Dr. MacFarland, and other witnesses who made those entries in their notes, were questioned at deposition, they said, well, we don't really know why that is there. And more or less, if we take the plaintiffs' view of it, they testified that they don't really see a basis for that notation to be there.

And then you've got Dr. -- and I'm going to forget how to pronounce the name, your expert?

MR. CHILDERS: Ashhab.

MR. LEWIS: Ashhab.

THE COURT: -- Dr. Ashhab saying, you know, I don't see that she ever had a problem on warfarin, so that was clearly still an alternative that she could have been on.

It seems that the evidence is that Dr. MacFarland treated her for was it like six years and had her on Pradaxa for the first three or four of that, and that Dr. MacFarland testified she did not have any significant bleeds from warfarin while. So if they develop that evidence, I don't see how I can keep them from offering that evidence.

If you've developed -- so I assume you've cross-examined these people, and there might be some further of discussion that. But whether or not she had a prior bleed on warfarin seems to me to be a question of fact. And although medical records from those first two years might be conclusive about it, nobody has got those records. At this point, I'm not inclined to blame either side for the absence of those records. And so it seems that the plaintiffs have got testimony essentially explaining what is otherwise in the chart from these two doctors, and I think they're entitled to do that.

I think you're certainly entitled in your

cross-examination of their experts -- if he says she never had a bleed on warfarin, I think you're entitled to probe that and ask about these histories. I don't know what all the testimony was by the various doctors.

Are they testifying live? Is MacFarland going to be here live?

MR. CHILDERS: That's not our plan, Your Honor.

THE COURT: All right. And who was the other -- was it the cardiologist who also --

MR. CHILDERS: Dr. Gunnalaugsson also had it in his records and said he didn't actually see --

THE COURT: Right.

So, I mean, it seems to me that -- I certainly believe you can challenge that, cross-examine him, but I don't believe that it's appropriate for you to blame the plaintiffs for failure of discovery and thereby preclude them from offering their evidence. Nor do I think it's appropriate that you be permitted to argue to the jury as counsel that, well, there was a failure to produce these records.

I think you can ask these doctors, have you seen these records, and they're going to say, I guess, no. But I think that's really as far as you can go.

MR. LEWIS: Okay. So if there are -- Your Honor, if there are an absence of -- for instance, Dr. Ashhab hasn't seen all of the providers' records during the entire time she

MR. LEWIS: It's their fault.

THE COURT: Yeah, exactly.

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              MR. LEWIS:
                          Okay.
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              THE COURT: So in that sense, then I'm going to deny
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      the motion.
              MR. LEWIS: That's fair guidance. Thank you, Your
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      Honor.
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              THE COURT: All right. Thank you.
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                          Then let's turn to the deposition
              All right.
      designations, and I think I said I would start with
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      plaintiffs.
              I got the reply -- or response, rather, filed by the
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      defendant. I read through it yesterday. I think I've got a
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      pretty fair grasp of the issues, but I do want to give each of
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      you a few minutes to just walk through each of these.
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              So let's start with -- is it Kliewer, is that her
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      name?
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              MR. CHILDERS: Kliewer.
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              THE COURT: Kliewer?
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              MR. CHILDERS: Kliewer actually.
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              THE COURT: Kliewer. All right.
              So, first, I haven't seen this transcript.
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      know what the document is that was referred to. I know --
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      I've read her deposition transcript, and I understand she was
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      questioned about it, but I don't think I've seen the document.
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      So it's a little hard for me to be sure what it is that she
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      was testifying about that day.
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MR. CHILDERS: It's a committee --

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              THE COURT: Well, obviously I interrupted you.
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      didn't really want to.
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              Is it Dr. Krudys, K-R-U-D-Y-S?
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              MR. CHILDERS: Correct.
              THE COURT: Is that who she referred to?
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              MR. CHILDERS: Correct.
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              THE COURT: So that's who she purported to quote from?
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              MR. CHILDERS: Correct. And Dr. Krudys gave a
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      presentation here.
              There were people from various entities, including the
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      government and Boehringer Ingelheim, who came to the advisory
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      committee meeting. And the purpose of the meeting is to have
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      them all talk about what they think about whether or not this
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      drug should be approved. It's not an FDA official
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      proclamation. It is a group of people that the FDA has asked
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      to come and speak to them about this drug, and they can say
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      whatever they want.
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              This happens to be before the drug was approved, as
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      you noted. And everything that was discussed at the advisory
      committee meeting, even the vote that the advisory committee
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      had, is nonbinding on the FDA.
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              So this is not an FDA official government document.
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      This is an unsworn transcript from which the defendant is
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      trying to put in hearsay as to what another person said.
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THE COURT: And Dr. Krudys --

MR. CHILDERS: Yes, sir.

THE COURT: -- was the rep -- he was a phar

THE COURT: -- was the rep -- he was a pharmacometrics reviewer for the FDA?

MR. CHILDERS: That's right.

THE COURT: Okay. And he was leading, I guess, the

Office of Clinical Pharmacology? That's part of the FDA?

MR. CHILDERS: Correct, and they have lots and lots of

THE COURT: Sure.

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offices.

MR. CHILDERS: He happened to be one of the people who made a presentation. He didn't put out an official FDA paper or proclamation. He gave a power point and talked about it. That's hearsay. That doesn't fall under the exceptions under 803 for a government record, and so our argument is it shouldn't come in.

We didn't object to the other stuff that is not hearsay. We just objected to her specifically talking about what another witness made with an out-of-court statement because she's clearly offering it for the truth of the matter, Your Honor.

THE COURT: All right. Thank you.

MS. JONES: Your Honor, with the Court's permission, our colleague, Mr. Hailey, who has been working on the deposition designation issues, will handle this argument.

THE COURT: Just make sure you slide a microphone

over.

MS. JONES: Thank you, Your Honor.

MR. HAILEY: Good morning, Your Honor. Nick Hailey.

So I just want to address sort of the nature of the advisory committee. I think what's -- your impression of the nature of this meeting is accurate.

This was a meeting that was convened by the FDA for the specific purpose of providing a recommendation in connection with the review and approval of Pradaxa. It was convened by the FDA pursuant to the Federal Advisory Committee Act.

(Off the record.)

MR. HAILEY: So the people that were part of this advisory committee and that attended the meeting, they were representatives from the FDA. They were independent experts who were special government employees for purposes of the meeting.

THE COURT: Is that what Dr. Krudys was?

MR. HAILEY: Dr. Krudys was a full-time employee of the FDA. He is a pharmacometrics reviewer. He not only presented at this meeting in advance of approval, he conducted the FDA's exposure response review as part of the approval process. And he actually authored one of their review memos that the FDA itself issued when, a month after this meeting, it approved this medicine.

So Dr. Krudys at this meeting is very much presenting on his investigation of the data on this medicine, his conclusions, his factual findings. He's expressing his view on the medicine. He's presenting on behalf of the FDA at this meeting, and later those views were expressed in the FDA review memo that he issued.

THE COURT: Well, that's one of my questions.

So if you've got the FDA approval, then why do you need a witness to testify what one of the reviewers said at a meeting?

MR. HAILEY: Well, we think that this is an important -- there's a question asked at the meeting about whether monitoring should be required, and Dr. Krudys responds directly to that question, and that's the specific portion of the transcript that Ms. Kliewer is asked about.

And he very clearly provides his view based on the data of whether monitoring should or should not be required, and that is captured in the advisory committee meeting in a clear way that we, ah, think is -- think is relevant and important here, that it's not captured in that same way in the memo that he later issues.

THE COURT: Well, that's what I was going to ask about.

So he doesn't say this in the context of the FDA's approval. In other words, it's not -- there's no memorandum

or similar statement from him as part of the FDA approval, formal approval, whatever that consists of?

MR. HAILEY: Again, his -- his memo that he issues at approval is sort of more focused on his exposure response analysis. It's much more sort of in the weeds. It's not this simple expression that he's having in this conversation at the FDA advisory committee meeting.

THE COURT: Okay. Anything else?

MR. CHILDERS: Your Honor, that's exactly the point, it's not part of what the FDA officially found. It's just him talking at a meeting.

If it had been in -- if this was the FDA memo that

Ms. Kliewer was testifying about, I wouldn't be standing here.

This is hearsay, and it shouldn't be approved.

THE COURT: I'm afraid I agree with the plaintiffs on this. I really appreciate the supplemental argument you made. It helped me a lot to understand and, to me, did make it a much closer question because I wasn't sure what this advisory council's role was.

But it does seem to me that the problem here is that, while the advisory council has a role, this is simply a statement by one of the participants in that council, even if he's got FDA authority in a forum. And I don't think it has the imprimatur of being government action in the sense that it's approved by the FDA or a statement by the FDA, and I

think that's what creates the problem under 803.

I think it does not become an official act or official record just because it's a statement made by even a government official at some type of a forum. I think that would open this rule far more than it is intended.

And because it's government, if the jury hears this and they're told, well, this is the official public record, this is an admissible statement because he speaks for the FDA, I think that that is troublesome. I think that that exaggerates the connection between his statement and his role.

So I'm going to sustain the objection. I won't allow that specific part that you've objected to come in because I do think it's hearsay.

All right?

MR. CHILDERS: Thank you, Your Honor.

THE COURT: The next one, this is -- I don't know how you say these names.

MR. CHILDERS: Can I stop you for a second?

THE COURT: Yes.

MR. CHILDERS: You will be happy to hear that's been withdrawn because we have reached an agreement on the testimony from Dr. Klaus Dugi.

And I do want to say this, Your Honor, as an aside.

Mr. Hailey and I spent four or five days solid on the phone
together and worked very cooperatively to limit the objections

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              And I wanted to just tell the Court how much I
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      appreciate how cooperative that was from the defense, and I
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      think it's really helped us to all come here ready to try this
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      case.
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              THE COURT: Maybe I ought to send you two back to see
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      if you can't settle this case. Probably not?
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              Well, so does that resolve all of the objections you
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      raised with Dr. --
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              MR. CHILDERS: Dugi. Yes, sir.
              THE COURT: Okay. Great. So I deny the objection
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      with regard to Dr. Dugi.
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              MR. CHILDERS: Okay.
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              THE COURT: Then next is --
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              MR. CHILDERS: Dr. Abdelgaber.
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              THE COURT: Abdelgaber.
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              I know what that one is about. I've got a pretty good
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      understanding of it. I'll let you make a brief argument if
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      you like.
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              MR. CHILDERS: Your Honor, the requirement for
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      causation opinion evidence and testimony in the Fourth Circuit
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      is that it must be more probable than not, and that mere
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possibilities are not relevant. They're not to go to the jury for the jury to consider, and that is why we've made this objection here.

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He clearly said this was a possibility. The prior

question and answer we did not object to where they talked about whether or not these other hospitalizations could have affected her health. But as soon as he said it's a possibility, not a probability, that made it inadmissible in a court of law, and that's why we've objected to that.

THE COURT: Well, I'm going to deny that objection. In think the argument kind of confuses the difference between what is admissible evidence and what is required in order to get an issue to the jury. And I think the cases you cited really stand for the proposition that in a causation context, let's say, is this.

The proponent has to get evidence sufficient for a jury to find that it's probable, reasonably certain or something like that. I don't think that it's necessarily the test for admissibility of an opinion. I think if this were the only opinion, and they had a burden to prove the probability of a fact, it would be insufficient. But I think they're the opponents here, and I think that they can use possibility evidence as a way of challenging your case.

In effect, the doctor says, well, it's possible, but he clearly doesn't think that is what occurred. But in either regard, it doesn't make the evidence inadmissible. It might not be enough on its own to get an issue to the jury, but I don't think that that precludes the admissibility. So I deny the objection.

MR. CHILDERS: Thank you, Your Honor.

THE COURT: Then the next one is Dr. MacFarland, and I'm going to say I'm confused about what to me is the essential fact that may or may not be at issue here.

I understood from my prior readings on all of this back when we were dealing with all these motions, and then from your objection, that Dr. MacFarland does not purport that she ever discussed the Pradaxa prescription with Ms. Knight or her family. And yet now I think in the response that they filed, they said, well, she does say that she may have had that conversation or did.

So in --

MR. CHILDERS: So she testifies -- the deposition was kind of interesting. We did not have the entire record. She found another record while we were in her deposition that sort of clarified what happened.

We all believed that Ms. Knight, her son and daughter made an appointment, went in and sat down with Dr. MacFarland to talk about being switched to Pradaxa.

THE COURT: Right.

MR. CHILDERS: When she was questioned, she said, I really -- I don't remember that. But if that is -- you know, I know we started her on the drug, I just don't remember that.

While we were there, she went and found another record that showed that the family actually met with her nurse, Nurse

Clagg, when they came in to get the prescription. So any risk benefit information they got would have been from the nurse.

After that, Dr. MacFarland continued to fill the prescription, but she didn't have the initial risk benefit discussion with them.

And so our objection is very limited. There's a lot of testimony in here that we did not object to about what she knows about Pradaxa, what she thinks about Pradaxa. The only things we objected to were hypothetical questions that were asked of her as if they were having that meeting, that initial meeting, and she was asked what would you have told Ms. Knight at that meeting?

That didn't happen, and so that's why we've objected to that very limited testimony.

THE COURT: Okay.

MR. LEWIS: Yes, Your Honor. Thank you.

Both of the plaintiffs in this case testified that they actually did meet with Dr. MacFarland, so there is a real issue of fact here, what exactly took place at the time the decision was made to switch from warfarin to Pradaxa.

I think the jury has got to make this determination and hear all of the evidence about that. But with respect to Dr. MacFarland's policies and practices, that's relevant to the issue of whether it's more likely than not that the risks and benefits were disclosed at the time of the switch.

But more importantly, the time of the switch is not
the only relevant time period here. If Dr. MacFarland
otherwise communicated with the plaintiffs at any time about
the risks and benefits of Pradaxa, then that would be relevant
evidence as well.

THE COURT: Well, let's take these things one at a
time.

MR. LEWIS: Sure.

THE COURT: With regard to that latter point, did Dr.
MacFarland testify that she had reason to believe that, at a
subsequent meeting with Ms. Knight or her family, perhaps to
renew a prescription or whatever, that she may have had those

MR. LEWIS: It's not clear from Dr. MacFarland's testimony that she did.

THE COURT: Okay.

conversations?

MR. LEWIS: It's somewhat equivocal based on the plaintiffs' testimony as to when they, if ever, talked to Dr. MacFarland.

THE COURT: All right. So it's really kind of the same answer to both.

MR. LEWIS: Correct.

THE COURT: So whether it was the first meeting or subsequent meetings, the kids testified that they were present when Dr. MacFarland discussed Pradaxa?

2.1 MR. LEWIS: Mr. Knight's testimony, and we cited this in our opposition paper, says there was an office visit with Dr. MacFarland where you talked about Pradaxa around this time. And then Ms. Stevens, who is the daughter of Betty Knight, testified about an October 2011 meeting between Dr. MacFarland, Mrs. I think Stevens -- or, no, Mrs. Knight and the plaintiffs to discuss the prescription for Pradaxa. So it's hazy about whether Dr. MacFarland was involved in this or not, but I think that's a jury question. I think the jury has got to sort out who was really talking to whom and what was disclosed, and they ought to hear all of the evidence about that. Otherwise, if we start taking away evidence, well, then Dr. MacFarland's entire testimony is irrelevant. I mean, if she's out, then she's got to be out entirely, including about any decisions about whether to monitor, about whether to change -- I mean, we've got to either go one way or the other.

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THE COURT: I don't know that that follows to me, but let me interrupt you because I think this is critical.

MR. LEWIS: Sure.

MR. CHILDERS: May I --

THE COURT: Is that what the Knights said?

MR. CHILDERS: So what both the children said was we

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      went to Dr. MacFarland and got the prescription. When they
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      were pressed further on page 54, for instance, on Rick
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      Knight's deposition, he was asked:
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              Do you have any independent recollection about this
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      office visit when this office visit took place with Dr.
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      MacFarland?
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              He said, No, I don't. And he also said, I don't
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      remember her telling me about any risks and benefits. So did
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      Claudia. They both said that.
              It all fits together with the fact that they knew they
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      went to her office and had it prescribed. None -- they don't
      remember any conversation --
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              THE COURT: Are they going to testify?
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              MR. CHILDERS: Yes, sir.
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              THE COURT: Okay.
              MR. CHILDERS: But they don't remember any
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      conversation actually occurring. They don't have any
      recollection of that, and it's because it didn't happen.
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              THE COURT: Have you all talked to the nurse? Has the
      nurse been --
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              MR. CHILDERS: We tried. She is out of state.
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      MacFarland said she didn't even know how we could get in touch
      with her.
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              THE COURT: All right.
              MR. LEWIS: But again, from our perspective, this is
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just a factual issue that the jury has got to figure out. And the policy and practices of Dr. MacFarland and her office are still relevant for the jury to consider, who is talking to whom and what was communicated and what's more likely than not to have been communicated when memories are hazy and recollections are fuzzy.

THE COURT: Well, you know, honestly it seems to me that I probably can't resolve this. If the predicate for the testimony from Dr. MacFarland that you want in is that the children said we had a conversation with Dr. MacFarland when she prescribed, then I'm going to let you use it. But if they testify that, no, it wasn't, then I don't think that you've got an independent basis for using this part of Dr.

MacFarland's testimony.

If --

MR. LEWIS: Well, we would probably have to impeach them with their deposition testimony.

THE COURT: Impeach them?

MR. LEWIS: Probably.

THE COURT: Oh, sure. I think you can.

MR. LEWIS: Okay.

THE COURT: Yeah, I'm not --

MR. LEWIS: Okay.

THE COURT: I think that is fair game.

MR. LEWIS: Okay.

THE COURT: But --

MR. LEWIS: I'm just concerned that Dr. MacFarland is going to be played before the plaintiffs.

MR. CHILDERS: I was going to say that, Your Honor.

That is going to happen. And so to the extent there is some way for us to resolve it -- I don't want to surprise anybody.

We're going to play her testimony before the children testify.

MR. LEWIS: But we could play the depo -- we could independently play the deposition testimony of the plaintiffs. Those are party admissions. I mean, we have the predicate already. So they can't -- they may be able to embellish upon the facts, but the admissions are the admissions, which we cited in our paper. So that's enough of a predicate to allow the MacFarland testimony to be played no matter what they say on the stand.

I could play that -- I could play those admissions in my case in chief, and that's a sufficient predicate for the evidence of Dr. MacFarland's testimony even if the plaintiffs get on the stand.

I guess what I'm suggesting is, it's not about waiting to see what the plaintiffs are going to testify --

THE COURT: I think you may be right. So they're the plaintiffs.

MR. CHILDERS: Yes, sir.

THE COURT: They are statements by a party. If they

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      made statements in a deposition that we met with Dr.
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      MacFarland about this prescription, then I think that that is
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      a sufficient basis for them to use this part of Dr.
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      MacFarland's testimony.
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              MR. CHILDERS: Understood.
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              THE COURT: So I am going to deny the objection based
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      upon the representations, as you've agreed upon really, that
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      the plaintiffs themselves, the Knight children, made these
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      statements to the effect that they met with Dr. MacFarland
      about the prescription.
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              MR. CHILDERS: Understood, Your Honor.
              THE COURT: Okay?
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              MR. CHILDERS: This is a great segue.
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              The last one --
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              THE COURT: Yes.
16
              MR. CHILDERS: -- Dr. Gunnalaugsson, there is no
17
      question, he never prescribed either coumadin or Pradaxa to
18
      Ms. Knight. And defendants are trying to elicit the same kind
19
      of testimony from him. What would you tell patients? What do
20
      you warn patients about when you meet? That's not relevant to
21
      this case because he unequivocally stated I didn't have any
22
      decision-making at all with regard to prescribing Pradaxa or
23
      warfarin to this particular patient.
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              And so for the same reasons you just denied it, I
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think you have to grant this objection.

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              THE COURT: All right.
 2
              MR. LEWIS: The testimony that -- if I recall
 3
      correctly, is about specifically communications with the
 4
      plaintiffs and Mrs. Knight, not policies and practices. I
 5
      think Dr. Gunnalaugsson's testimony is specific about
 6
      communications with the plaintiffs themselves and Mrs. Knight.
 7
              THE COURT: Well, I read through this, the excerpts,
 8
      you know, the part you all identified, and I don't recall
 9
      seeing that.
              I thought -- I think there were three matters --
10
11
              MR. CHILDERS: Right.
12
              THE COURT: -- to which there were objections.
13
              And the first was about his testimony about the risks
14
      of Pradaxa if he's prescribing it. I thought there wasn't any
      indication there that he would have -- he didn't prescribe
15
16
      Pradaxa. I didn't think there was any indication that he
17
      would have had any reason to have that discussion with the
18
      Knights.
19
              So, as to that, I didn't see how -- am I missing
20
      something?
21
              MR. LEWIS: And my -- I think there is two issues
22
      about -- there's no question that there was not an actual
23
     prescription by this physician.
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              THE COURT: Okay.
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              MR. LEWIS: But that doesn't end the inquiry as to
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whether there was a communication --
 1
 2
              THE COURT: Right.
 3
              MR. LEWIS: -- between anyone and the plaintiffs.
              If the plaintiffs were warned by anyone, a home health
 4
      care provider or a doctor that didn't prescribe Pradaxa, about
 5
 6
      the risks of Pradaxa --
 7
              THE COURT: Sure.
              MR. LEWIS: -- that is still relevant to causation.
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 9
              THE COURT: I agree.
10
              But now we're talking about Dr. --
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              MR. CHILDERS: Gunnalaugsson.
12
              THE COURT: -- Gunnalaugsson, and he was an
13
      interventional cardiologist.
14
              And where I understood the first of the plaintiffs'
      objections, I made notes kind of in quotes that he testified
15
16
      about what he perceived the risks of Pradaxa to be when he's
17
      prescribing it. But that he did not purport that he had such
      conversation with any of the plaintiffs.
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19
              MR. LEWIS: Well, the specific testimony is on page
20
      111, 1 through 18.
21
              THE COURT: All right. Let me get up with you here.
22
              111 -- oh, okay. Wait a minute.
23
              MR. LEWIS: So that is at least what I was referring
24
      to. Because what Dr. Gunnalaugsson is saying is that, because
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      Mrs. Knight was having some trouble understanding based on
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perceived dementia or whatnot, he was having communications with the son and has a recollection of the son having an understanding about the risks of Pradaxa.

MR. CHILDERS: Your Honor, I was kind of going in reverse order. I think that's why we are a little confused here --

THE COURT: Okay. All right.

MR. CHILDERS: -- because it segued I thought from the last argument.

THE COURT: All right. So --

MR. CHILDERS: We had three different objections.

THE COURT: Yes. Okay. I am glad you clarified that.

MR. CHILDERS: I apologize.

THE WITNESS: Well, let's take the one that we've addressed first. So it does seem to me that his discussion on this page, to which you objected, he does purport that he had discussion with the son and her or her.

MR. CHILDERS: He doesn't actually say that, Your

Honor. And this is -- and just so you understand, Dr.

Gunnalaugsson answered lots and lots of questions that were
never asked of him. This happened to be one of them.

And he says son was aware of it, and he says why -- he was asked why do you say that? And he says because we talked about it. But then he changes and says he was aware of it, and she seemed to understand, too. I don't know how to grade

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      her dementia basically.
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              And then he says they were fully aware that she had
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      chronic GI bleed, and that this would increase her risk, but
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      he doesn't say he actually discussed that with them.
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              THE COURT: Well, you know, if you're going to use the
 6
      deposition, I'm going to deny the objection as to this point.
 7
              I think --
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              MR. CHILDERS: Okay.
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              THE COURT: -- it's close enough that the jury should
      hear and decide for itself what they think about that.
10
11
              MR. CHILDERS: Understood.
12
              THE COURT: So that part I'll deny.
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              MR. CHILDERS: The next part, Your Honor, he's asked
      if he would utilize a particular coagulation test for a
14
15
      bleeding patient.
16
              THE COURT: Right.
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              MR. CHILDERS: He didn't treat her for her bleed --
18
              THE COURT: Right.
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              MR. CHILDERS: -- and so we don't believe that is
20
      relevant.
              THE COURT: So how does the defense believe this is
21
22
      relevant?
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              MR. LEWIS: It's really more, Your Honor, beyond
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      whether this physician treated for the bleed. It's whether
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monitoring is necessary or not even absent a bleed --

THE COURT: Well, but now aren't you spilling over into asking him what should be an expert opinion? I mean, he is an expert, he's got opinions, but that doesn't make him an expert for the defense to introduce his opinion evidence about matters outside of his treatment.

MR. LEWIS: It's actually more about causation.

THE COURT: Okay.

MR. LEWIS: So this physician was her treater during this time frame. He was her cardiologist. And if that physician is saying, hey, this isn't going to be helpful to me, this aPTT test, then that's relevant to causation.

Because what the plaintiffs are arguing is, hey, you should have been doing aPTT testing all long, and that would have guided treatment of this particular plaintiff and avoided a bleed event. And this doctor is saying this isn't -- I wouldn't even do this.

THE COURT: I'm going to grant this objection. I think this is one of those times where the use of his testimony spills outside of the scope of his treatment in that this was not -- he was not testifying about a decision he made in the course of her treatment. He's offering opinions about how would he would address certain matters, but I think it's outside of the treatment. And since it's outside of the treatment, I don't think you get to convert him to an expert on causation or anything else. It goes beyond his treatment.

So I'm going to grant that part.

And then the last, which I guess is where you were to begin with, where --

MR. CHILDERS: Yes.

THE COURT: -- he testified about the fact that he hadn't prescribed warfarin for two or three years.

MR. CHILDERS: Right. He never prescribed warfarin to this patient at all. He didn't prescribe any anticoagulation to Ms. Knight. So whatever his personal practice was is irrelevant for one, for that purpose.

And also he's talking about the last two or three years, which is after Ms. Knight has already died. That can't possibly be relevant to what happened during her lifetime.

THE COURT: Okay.

MR. LEWIS: Well, again, Your Honor, it's very similar to when the Court was ruling on our summary judgment motion. The Court found that, for instance, Dr. MacFarland's testimony that she would have made some different treatment decisions -- again, all speculative because we're talking about alternative scenarios here that didn't actually occur -- Dr. MacFarland would have treated the patient differently with certain information, this is the same principle.

What the plaintiffs are arguing here is that Mrs.

Knight should have been on warfarin instead of Pradaxa. And if -- and this is her cardiologist. This is the guy making

that call for her, and this guy making the call says, I would't have made that call. And that's very, very critical to the specific warning cause. It's not an opinion, it's specific warning causation just similarly to what the Court ruled -- or relied on in the summary judgment motion.

THE COURT: Well, I disagree.

You know, I guess this gets to be a close question if you have a doctor who testifies that I considered different things, and here's what I decided. I think when he testifies that he considered things at the time of the treatment -- for instance, if he had testified, you know, when she was my patient, I knew she was on Pradaxa. I thought about warfarin, but I wouldn't prescribe -- decided not to prescribe it. I think that is admissible, I think that is part of his treatment.

But I think this goes outside of that because this is just asking him to express an opinion that was not formed at the time of and as part of the treatment. And I guess maybe that is for better or for worse, maybe hopefully a little clearer articulation by me of where I think we draw the line on what a treating doctor can testify about who is not being converted into a party expert beyond the treatment.

MR. LEWIS: And not to ask the Court for -- my understanding, then, from Your Honor is that it's really because of the time frame that he is talking about, which is

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      two to three years, and not back when he was making real-time
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      decisions?
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              THE COURT:
                          Yes.
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              MR. LEWIS:
                          Okay.
 5
              THE COURT:
                          Yes, that's part of it.
 6
              MR. LEWIS: Understood.
 7
                          I think what he raised about whether this
              THE COURT:
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      opinion is even an opinion he held during the time of
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      treatment, I think that's a fair issue. But, yeah, I think
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      this is not a judgment that he made during the course of and
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      part of the treatment, so I'm going to grant that objection.
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              MR. CHILDERS: That was our final objection.
              THE COURT: So here's what I'd like for you to do,
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14
      then, after we conclude.
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              I want the parties to get together and go back through
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      these depositions and, based upon my rulings, make sure that
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      you know and agree what's in and what's out so that we don't
18
      have a problem later on.
19
              And how are you going to -- are these video
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      depositions?
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              MR. CHILDERS: Yes, sir.
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              THE COURT: So I assume --
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              MR. CHILDERS: Gina Veldman back here will be taking
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      care of all that for us.
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              THE COURT: All right. And then so how do you
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      intend -- do you intend to excerpt those portions that I've
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      sustained and just delete them?
              MR. CHILDERS: You would be amazed at what she can do
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 4
      with these video transcripts.
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              THE COURT: Probably make a witness say anything she
 6
      wanted them to.
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              MR. CHILDERS: Unfortunately she can't do that, and we
      wouldn't ask her to do that.
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 9
              But she is very good at what she does, and we are
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      working with them -- I'm sorry.
11
              Well, we don't really need to get into the
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      technicalities of it.
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              THE COURT: I'll trust --
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              MR. CHILDERS: We've done this a few times now, and
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      we're all pretty comfortable with how it goes.
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              THE COURT: Okay. Very good.
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              All right. Let's go to the defendant's objections to
      the plaintiffs'.
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              MR. CHILDERS: Is it okay if I stay here?
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              THE COURT: Yes, you may.
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              MR. CHILDERS: Okay.
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              THE COURT: I'm going to start by turning to your
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      opponent. Tell me what you think is relevant and admissible
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      out of this launch video.
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              MR. CHILDERS: Your Honor, the launch video is
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basically the company getting together all of their sales reps to encourage them to push this drug on doctors and patients around the country. And the launch video shows that the entire drive that they at least edited -- this is not edited by me or anybody on my team, this is how we got it from BI -- is money.

They talk about how much money this is going to make for the company, what a blockbuster drug it's going to be. They asked sales reps, who are agents of the company, what they think. Everybody who speaks on the video is an agent of the company. They work for the company. There's only one person in the entire video who says we're going to help patients.

I think that's relevant, Your Honor, because we have to prove by clear and convincing evidence that, in this case, we believe Boehringer put profits over patient safety. This is clearly evidence of that from the beginning. This is before the drug was even on the market.

They gathered all of their folks together. They had this big, huge, celebratory meeting. And when they cut the video to send to us, for whatever reason, these were the most important parts that they left in the video.

THE COURT: Well, since I've bifurcated the punitive claim, why should this be allowed during your liability phase and not --

MR. CHILDERS: Well --

THE COURT: -- pushed to the punitive phase if we get to that?

MR. CHILDERS: We have to get there first, and this is evidence of the company putting profits over patient safety. The jury has to check the box first before we get to damages, punitive damages. This is clear evidence of the company putting profits before patient safety and we believe will allow the jury to see that that box should be checked.

When we move on to punitive damages evidence, my understanding, Your Honor, is we're talking about money, just money. We're not talking about the actual acts. We have to show the acts to get us there in the first phase of the trial. Otherwise we don't get to phase 2 of the trial, at least that is my understanding of how I've done it in the past.

And so this is an admission of the company. It's their document. They produced it. It's all of their people in the video. And it's made by them. We believe it's relevant specifically for the issue of whether or not punitive damages should be awarded, and that's why we think it should be admitted.

THE COURT: All right.

MR. HAILEY: So we obviously disagree on the relevance. We don't believe that this video is remotely relevant to plaintiffs' claims.

This same video plaintiffs have sought to introduce into evidence in the first two Connecticut Pradaxa trials that have been held to date. In both of those cases, this video was precluded on a number of grounds, including that it is not relevant.

THE COURT: Is that other trial still going on?

MR. CHILDERS: Yes, sir.

THE COURT: Was it used there?

MR. CHILDERS: No, sir.

MR. HAILEY: And, Your Honor, we've submitted as Exhibit 1 and 2 to our objection brief the Connecticut rulings, but I just want to highlight the language from the first Connecticut court's ruling because I think it really encapsulates our view. And this is reading from the order.

There are no statements made in the video to suggest that any particular act or omission by the defendant that is relevant to this case was driven for financial reasons. The court finds that the vast majority of the video is irrelevant under Code Section 42, which is the Connecticut equivalent to Federal Rule of Evidence 402.

THE COURT: Well, I've read those decisions. I'm going to grant the objection. I don't believe you can use this launch video in your case in chief. If we get to a punitive stage, I think I would let you use it then.

MR. CHILDERS: Okay.

THE COURT: But I think it is largely irrelevant. And to the extent it has any probative value, it is greatly outweighed by the prejudice.

Companies are expected to motivate a sales force to sell their product, and I don't think that the fact that this is -- the focus of this launch video is on the salespeople, I think the jury shouldn't misconstrue, and I think that it is a risk that they might. So I grant the objection with respect to the launch video.

MR. CHILDERS: Understood, Your Honor.

MR. HAILEY: And, Your Honor, if you wouldn't mind.

In terms of punitives, I think BI would maintain its objection that this launch video is not relevant to punitive damages.

THE COURT: If we get to that point, we'll have a chance to take that up again.

MR. HAILEY: Okay. Thank you.

THE COURT: All right. Next was Kliewer's testimony about the fact that at the time of her deposition, the company had not submitted any of this putative therapeutic range data, but did so later.

Apparently you all worked out some type of a stipulation on this in other cases, is that --

MR. CHILDERS: I did not, Your Honor. Separate counsel did that.

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THE COURT: All right.
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MR. CHILDERS: Mr. Moskow was involved in that trial, but he's not the lead counsel either.

THE COURT: Okay.

MR. CHILDERS: That case is still ongoing now. So -I wasn't involved in that.

THE COURT: Okay.

MS. JONES: And just to confirm that --

THE COURT: Make sure that microphone is on.

MS. JONES: Thank you so much. And good morning.

11 Phyllis Jones for BI.

The history on this, and really the history is part of what motivates our motion on this testimony, is in the first two trials, Ms. Kliewer's testimony was played for the jury, both her testimony from 2014 and then portions of her testimony from 2017. And what happened in both of those trials in Connecticut is that counsel for plaintiffs then got in front of the jury during closing argument and said BI did not submit this information to the FDA. Which we know to be incorrect based on, for example, Appendix B to the brief that we submitted to Your Honor.

And so we have become concerned not so much about the testimony, but the way that the testimony has been used in the course of the trials to date, to make what is we think admittedly a provocative claim to the jury that the company

somehow failed to provide important information to the company -- to the FDA regarding the safety of the medicine when we know that not to be supported by the evidence.

THE COURT: Well, can't you remedy this by putting that into evidence in your case?

MS. JONES: Well, certainly we can do that, Your Honor, but we're concerned about arguments like the ones that we've heard in some of the earlier cases that really do not acknowledge that actual fact of the evidence, that the company did in fact submit this information to the FDA.

Now, in the third trial in Connecticut, you've rightly picked up on from the briefing that what they did was, right after Ms. Kliewer's testimony was played, the parties had reached a stipulation that was relatively short that essentially laid out the history there. We think at a minimum, if plaintiffs are permitted to play this testimony, that there needs to be some kind of instruction from the Court consistent with what we submitted as part of our proposed instructions, that makes clear to the jury what the actual history was here.

THE COURT: Well, why don't you submit evidence to the jury in your case about the post-2014 submissions? And then if they try to make the argument -- I can't stop them from making an argument if it's belied by the evidence. You can point that out to the jury, and it seems to me that is your

remedy here.

Your remedy is to submit evidence that shows that while Mrs. Kliewer might have been correct at the time, we did later submit all of these things.

MS. JONES: Well, I guess a couple of responses to that, Your Honor.

The first response is that the evidence that would be necessary to address the type of representation that we've heard made in the first two of the Connecticut trials would actually compound the prejudice to the company. Because the evidence related to the submission of the information brings in a whole set of articles that were published about, again, what we believe was an incorrect claim about the company withholding evidence from the FDA.

And so our only remedy to addressing that type of representation is having to bring in evidence that further complicates the prejudice to the company.

We certainly think it's within the power of the Court to preclude counsel from making a representation to the jury that we know to be false based on the actual documentary evidence in the case, and that's all we're asking for.

MR. CHILDERS: Your Honor, I disagree.

The reason that they're making this motion is because the evidence that they would have to put on shows that they sent the FDA three articles that were published in the British

Medical Journal that are scathing about Boehringer Ingelheim.

And when they submitted those to the FDA, they submitted them

with a press release that says, this is all not true.

That is not the same as giving the FDA the information that Ms. Kliewer in 2014, a year after Betty died, said we haven't given that to the FDA.

I agree with you. If they have evidence to show they specifically gave it to the FDA, they should put it on. We have sworn testimony from their own witness who said I didn't give it to the FDA.

THE COURT: So counsel can argue the evidence. And if at the end of the day the only evidence by either side about what was submitted is the evidence that they've cited in her 2014 deposition, they're entitled to make that argument because that's what the evidence says.

If they submit her deposition, which I take it you're going to offer --

MR. CHILDERS: Yes, sir.

THE COURT: -- you've got to respond with evidence.

And if that opens other doors that are troublesome or a problem for you, that is the way evidence works out.

I don't think I can require them to enter into a stipulation, and I can't preclude them from making arguments based upon the evidence. If at trial there is evidence from your side of what you submitted, then if he makes the argument

on behalf of the plaintiffs that there was no submission, you've got evidence, and you can tell the jury he's obviously wrong. If instead what it sounds like there's a dispute in the evidence and between the parties as to the facts as to the nature of the subsequent disclosure to the FDA, that is for the jury to decide.

So I'm going to deny the objection.

Next, I guess, are the references to the e-mail that Dr. Connolly sent. I guess this is the e-mail where he talks about there being perhaps a therapeutic range, 40 to 200 or whatever. And I take it that there were at least three different witnesses in whose depositions or trial or use at trial that this was discussed.

So --

MS. JONES: And, Your Honor, again with the Court's permission, our colleague, Ms. Perez, will argue those issues.

THE COURT: Absolutely.

MS. PEREZ: Good morning, Your Honor. Jessica Perez for BI.

Yes, so this e-mail was written by Dr. Connolly in the context of having received an early draft of the Reilly exposure paper. And Dr. Connolly responds and appears to at least in this e-mail support the idea that there should be a therapeutic range for Pradaxa.

THE COURT: Now, as I understand it, Connolly was one

of the people involved in the RE-LY study, but he's not a BI employee or agent at the time that he makes -- sends this e-mail?

MS. PEREZ: That's correct. He is a professor at McMaster University in Ontario and a practicing cardiologist who was involved in the RE-LY study.

And we're objecting to this e-mail and related testimony based on hearsay. I mean, this e-mail is being presented for the truth of his statement, that there is a therapeutic range for Pradaxa, and that patients should be maintained within that range. And it should be excluded on that basis.

THE COURT: Okay.

MR. CHILDERS: Your Honor, Dr. Connolly was the principal investigator for the RE-LY trial. He also is a co-author of the article that this e-mail is talking about. He co-authored it with Dr. Reilly and several other people who work at Boehringer. His opinion is clearly relevant to the case as to whether or not this should be included in the e-mail.

I do believe for purposes of what was happening there, he's an agent of the company. He is working with them, and he is drafting a paper with the -- with the entire RE-LY group, including the BI employees. And so I think it's an exception to the -- to hearsay.

THE COURT: From the way you're describing it, I don't think that you have enough for the foundation to attribute this statement by Connolly to be a statement of the party. So unless you've got something more -- the fact that he was involved in the RE-LY study and that it was in some sense continuing I don't think is enough by itself to make him an agent for BI such that his out-of-court statement would be attributable to them.

MR. CHILDERS: Well, they pay him, Your Honor. That makes him their agent. They paid him to do the study and to help write the paper. That's no different from an employee for this purpose.

THE COURT: Okay. What about that?

MS. PEREZ: Many, many practicing doctors are involved in clinical trials, some in a major way, and collaborate with employees of pharmaceutical companies on published articles.

And so that mere involvement in research activities doesn't make a doctor an agent --

THE COURT: Well, he's going beyond your involvement. He's saying he was paid by BI for the work that included what he discussed in this e-mail.

I mean, if that's the case, it seems to me that is -MS. PEREZ: I don't think that that is in the record,
that Dr. Connolly was paid to author the article.

THE COURT: Well, here's what I'll do. For now, I'll

hold this in abeyance. Find where you have in the record, that is admissible evidence, evidence that converts him from just being a collaborator to being effectively an employed agent for these purposes on behalf of BI.

I think the fact that he's in the RE-LY study and all that, that makes him a great expert. It doesn't convert him to their spokesperson, so to speak.

MR. CHILDERS: Understood, and I will get that for Your Honor.

THE COURT: Okay. So I'll hold off on that until you can -- obviously whatever you can get to me, show to the defense, and we'll see if we need to have further discussion or not.

MR. CHILDERS: Yes, sir.

THE COURT: Okay?

Next, Dr. Eberle.

MS. PEREZ: Yes.

The testimony that we're objecting to of Dr. Eberle relates to a 2017 European regulatory document that describes a study that was performed in the European Union to assess the effectiveness of patient and doctor education materials that were distributed in the European Union.

THE COURT: So this study led to some type of alert; is that correct?

MS. PEREZ: The materials were created, and then the

study was more of a post-hoc study to determine whether or not those materials helped doctors.

THE COURT: Okay

MS. PEREZ: And we're objecting to this just based on relevance. This is a European regulatory document. It studies materials that were only distributed in Europe, which dealt only with the 110- and 150-milligram doses.

And perhaps more importantly, these materials weren't even created or studied until after the death of Ms. Knight.

MR. CHILDERS: Your Honor, Mr. Moskow is going to handle this one.

THE COURT: All right.

MR. MOSKOW: Good morning, Your Honor. Good to see you again. Neal Moskow for the plaintiffs.

Your Honor, let me start by saying that the information in question looks at whether providing specific risk information to both physicians and directly to patients increases the safety of the drug. And they not only concluded that it did, but before the results were finalized, there was a plan to roll this out in the rest of Europe.

The planning for this, as Dr. Eberle testified to in his deposition, started more than five years before his deposition. So his deposition was taken in 2017. That puts us at 2012. So the ideas behind this study predate the bleed.

And that's particularly relevant here because in West

Virginia, the law at the time of this bleed, BI had the duty to warn Ms. Knight directly.

THE COURT: So remind me who Dr. Eberle was.

MR. CHILDERS: Dr. Eberle is a pharmacovigilance safety officer. In the vernacular of the pharmaceutical industry, it's his responsibility to ensure that the product is safe once it is out in the marketplace. So he headed up a team of scientists, including physicians, that would survey the literature, review adverse event reports and determine whether or not there were safety issues with the drug that needed further evaluation.

THE COURT: On behalf of BI.

MR. CHILDERS: On behalf of BI.

So based on his deposition testimony -- I can provide it to the Court at page 99 -- he indicates that, you know, five years before his deposition, that they had identified these issues, and they were planning the study.

And, again, because of the peculiarities of West
Virginia law at the time of this bleed, BI had the duty to
warn Mrs. Knight directly. And the issue that this paper or
this study demonstrates is, first of all, knowledge of the
company that this was an issue; second, feasibility, that they
had a way to communicate directly with patients that would
improve safety; and, third, that once they got around to doing
the work, it proved up that that was a fact.

So it goes to the failure to do this, you know, basic investigation in time to save Mrs. Knight.

THE COURT: Okay.

MS. PEREZ: It's just -- it appears that plaintiffs' argument, I guess, boils down to the fact that because the practices in Europe were different from the practices in the U.S., that that somehow makes BI's label inadequate.

I mean, the central question in this case is whether the information provided to Ms. Knight provided an adequate warning of the bleed risk.

THE COURT: And to me, I think I agree with plaintiff.

This is evidence as to the state of their knowledge at and

prior to the time of her event. So if BI had knowledge,

because Dr. Eberle was involved in this process, then it seems

to me that is relevant.

MS. PEREZ: The study -- Attorney Moskow described the planning for the study began before her death, but the materials that were developed and tested in Europe were not distributed or studied until after her death.

THE COURT: Well --

MS. PEREZ: And so the knowledge -- it does not seem to prove that BI knew anything at the time that is relevant for this lawsuit.

MR. MOSKOW: I think that the basic statement there, Judge, is that they understood that if they gave more

knowledge to patients, it would improve the safety of the drug. And they knew that, that's why they designed the study, and it was so successful that they have rolled it out in the rest of Europe.

THE COURT: Well, if it's relevant to BI's knowledge and feasibility of further warnings at or prior to her death, why not stop there with the evidence and not have further testimony about the ultimate results of a study that didn't take place or at least didn't get completed until well after her death?

MR. MOSKOW: Because, Your Honor, the data showing that warnings matter is part of the plaintiffs' burden here. We have to -- as the Court has identified in the pre-charge or the preliminary charge, that plaintiffs' burden is to show that a better warning would have made a difference. And so the jury is entitled to hear that when Boehringer gives a better warning, it does make a difference.

MS. PEREZ: This, again, seems to boil down to an argument that because information was provided in the European label that was not provided in the U.S. label, that that somehow makes BI's label inadequate. And the Court has said, when it denied Boehringer's motion to exclude foreign regulatory evidence, that that was not an appropriate argument for the plaintiffs to make.

And in addition, the feasibility of providing warnings

is not an issue in this case. BI does in fact provide warnings to patients, both in the form of the prescribing information for the doctor and the Medication Guide that is included, which goes directly to patients. But those warnings abide by the regulations here in the U.S. as opposed to the regulations in Europe.

THE COURT: Well, I think what this speaks to in terms of feasibility is the content of the warning, not just whether -- not some warnings would be effective.

I'm going to deny the objection. I would certainly entertain a limiting instruction, if you want to offer one at the time. I do think this is evidence which is admissible as going to BI's knowledge at and prior to the time of her death and to feasibility of the content of the warning.

I think if you believe that the jury might somehow misconstrue this, I would certainly give a limiting instruction.

Since you've mentioned it, I'll reaffirm my ruling that I do not believe that plaintiffs can use the foreign regulatory approval or process as evidence here, and I think this is outside of that. So I deny that objection.

Then last is Dr. Corsico. Explain this one to me.

MS. PEREZ: Yes.

Your Honor, the testimony that plaintiffs have designated from Dr. Corsico is just a few lines that is pulled

1 out of a larger series of questions dealing with a different 2 plaintiff who was the subject of a different lawsuit. THE COURT: And who is Dr. Corsico? Remind me. 3 4 MR. CHILDERS: He is a BI employee. He was a 5 cardiologist who worked on the drug. 6 THE COURT: Right. 7 The portion of the deposition involved the MS. PEREZ: 8 questioner asking Dr. Corsico to assume facts about a patient 9 whose records he had not previously seen and to answer 10 questions based on those assumed facts. 11 And this was some male patient who had, I 12 quess it was described as a similar cascade of events that --13 MS. PEREZ: Yes. 14 THE COURT: I don't know who came up with that phrase, 15 but basically testimony from Dr. Corsico that a different 16 patient had sort of a course similar to the course that 17 plaintiff believes occurred with respect to Ms. Knight 18 generally. 19 MS. PEREZ: Generally, but there are some key 20 differences. 21 THE COURT: Okay. 22 So the way this question proceeded, the MS. PEREZ: 23 questioner asked Dr. Corsico if he could agree that this 24 person died from this series of events, and he explained that

he could not give a specific medical opinion on the patient

25

not having seen the records.

And in that context, the questioner asked whether it was possible for a series of or cascade of events precipitated by a GI bleed to lead to someone's death, and Dr. Corsico agreed to that.

But the context in which he answered that question is very different from the context we're dealing with in this case. The facts that were described to Dr. Corsico involved a patient who had undergone major surgery to have part of his colon removed to treat his GI bleed, who was never discharged home, and who died, you know, within a month. That's very different.

The meaning of the words cascade or series of events are very different than this case, in which we are dealing with a patient who never underwent major surgery for her GI bleed, was discharged home, and died more than three months after the cessation.

THE COURT: Okay.

MR. CHILDERS: Your Honor, I would agree with Ms.

Perez if the question asked do you believe that the series or cascade of events could have caused Mr. Higgins' death.

That's not what he was asked. He was asked a very general question generally, and I'll read the entire question to you.

Okay. Well, do you understand that there can be a series or a cascade of events that can ultimately lead to

54 1 one's demise that may be precipitated by a gastrointestinal 2 bleed, right? 3 And he answers: Yes, sir. 4 THE COURT: All right. I'm going to sustain the I think in this instance, it is much too vague and 5 6 presents what I think might be a very confusing scenario to 7 the jury. 8 I don't think there is enough in this question to make 9 this sufficiently similar to the pattern that you've claimed with regard to Ms. Knight to make this relevant evidence. 10 11 if it's even close, I think it's much more likely to result in 12 confusion. So I'm going to sustain or grant that objection. 13 All right. Does that take care of -- that's all I had on my list for these objections to depositions. 14 15 MS. JONES: I think that's all we had, Your Honor. 16 THE COURT: Okay. Are there any other contested 17 issues that the parties are aware of before we -- motions or evidence, matters or things like that, exhibits? 18 19 MS. JONES: I don't think so, Your Honor. 20 THE COURT: Okay. Have you had a chance to look at 21 the proposed voir dire and preliminary instructions? 22 MS. JONES: We have. 23 MR. MOSKOW: Yes.

discuss with regard to either of these?

THE COURT: Before we get into it, do you have much to

24

25

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MR. MOSKOW: Your Honor, on the plaintiffs' side, we
 1
 2
      have two issues with the proposed charge and three with voir
 3
      dire or visa versa.
 4
              THE COURT: Okay. And what about you folks?
 5
              MS. JONES: We have some issues, Your Honor.
              THE COURT: All right. Then we're going to take a
 6
 7
      brief recess. I've got to get my copies of these documents
 8
      anyway.
 9
              MS. JONES: Thank you.
              THE COURT: We'll take a 10-minute recess.
10
11
          (Recess taken from 11:03 to 11:15 a.m.)
12
              THE COURT: All right. Let's start with the voir
13
      dire, and I'll listen to the plaintiffs first.
14
              MR. MOSKOW: Thank you, Your Honor. Neal Moskow for
      the plaintiffs.
15
16
              Your Honor, with regard to voir dire -- and I can
17
      submit these in writing. I just wasn't sure what Your Honor's
      preference was.
18
19
              But specifically with regard to the voir dire, Section
      Bla, which identifies the lawyers --
20
21
              THE COURT: Okay.
22
              MR. MOSKOW: -- we would propose, based on the
23
      conversation we had off the record, to excise --
24
              THE COURT: Yeah, we'll take Harry's name out of it.
25
              MR. MOSKOW: Thank you, Your Honor.
```

1 We would also seek to excise the two attorneys from 2 the Salim Beasley office who are no longer actively involved 3 in the case. So that would be Lisa Causey and Robert Salim. 4 THE COURT: Okay. 5 MR. MOSKOW: Your Honor, the only other issue that 6 we'd like to raise with regard to the voir dire has to do with 7 Section E8. And the question reads: Are you willing to judge 8 witnesses who work for a pharmaceutical company in the same 9 way that you would judge any other witness? 10 Our position is, Your Honor, that singles out a 11 specific witness and should not be asked. If the Court is 12 inclined to ask such a question, we would ask for a mirror 13 image charge or question to the effect of, are you willing to 14 judge the witnesses who have sued a pharmaceutical company in 15 the same way you would judge any other witnesses? 16 Okay. What's the defense say on those two 17 possibilities? 18 MS. JONES: We discussed this over the weekend. 19 apologize. 20 We've discussed this over the weekend. We have no 21 objection to that addition if the Court is okay with it. 22 THE COURT: All right. So your position would be to 23 give the corresponding question? 24 MS. JONES: Yes, Your Honor. 25 THE COURT: And that satisfies you?

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57
 1
              MR. MOSKOW: It does, Your Honor.
              THE COURT: All right. We will add that question,
 2
      then, as No. 9 and then renumber the remaining --
 3
 4
              MR. MOSKOW: Those are all the issues the plaintiffs
 5
     have, Your Honor. Thank you.
 6
              THE COURT: All right. Let's hear from the defendant.
 7
              MS. JONES: Your Honor, also fairly limited
      suggestions on the voir dire.
 8
 9
              As to the listing of defense counsel in section Bc, we
      wanted to just cut some of the folks from the list.
10
11
              And, of course, we can submit this --
12
              THE COURT: Yeah, why don't you do that.
13
              MS. JONES: -- if that would be helpful.
14
              THE COURT: Give them to Blake, and he'll take care of
      it.
15
16
              MS. JONES: Okay. We'll do that. Should I go through
17
      the list now?
18
              THE COURT: Do you have a corporate representative
19
      that you have decided upon?
20
              MS. JONES: We don't -- we will not have anyone
21
      sitting at counsel table.
22
              THE COURT: Okav.
23
              MS. JONES: Ms. Danielle *Devine will be in the
24
      audience, and I will probably introduce her, but she won't be
25
      sitting at counsel table.
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1
              THE COURT: All right.
 2
              MS. JONES: So I suspect that could probably come out.
 3
              THE COURT:
                          We will just take that out, then, if
 4
      you're not going to have anybody at the table.
 5
              Okay.
 6
              MS. JONES: Your Honor, did you want me to read
 7
      through the lawyers who should come out of the list or just --
 8
                         Just give that to Blake when we are
              THE COURT:
 9
      finished.
              MS. JONES: Okay. The only addition that we would
10
11
      suggest to the substantive questions would be in Section D.
12
      We had proposed to plaintiffs adding a question about Plavix:
13
              Have you, a family member or a close personal friend
14
      ever been treated with the drug Plavix? If so, who? What was
15
      the reason for the prescription? Please describe the person's
16
      experience with the medication and current health condition.
17
              THE COURT: And why do we need to add --
              MS. JONES: Because Plavix was also a medicine that
18
19
      Mrs. Knight was on at a certain point during her life and is a
20
      medicine that carries a risk of bleeding as well.
21
              THE COURT: Okay. What's plaintiffs say to that?
22
              MR. MOSKOW: We have no objection to adding that, Your
23
      Honor.
24
              THE COURT: All right. We'll add, then, the
25
      corresponding question about Plavix.
```

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1
              MS. JONES:
                          Okay. And we can send that as well, Your
 2
      Honor.
 3
              THE COURT: All right.
 4
              MS. JONES:
                          Those were the only issues that we had on
 5
      the voir dire.
 6
              THE COURT: Okay. Then we'll make those changes.
 7
              Let me comment. You've got the questionnaire, the
 8
      supplemental questionnaire that the Court sent out. What I
 9
      propose we probably have to do, as I've included those
10
      questions on the voir dire, is to ask those questions again
11
      orally here in the courtroom.
12
              We know a number of people have responses. Hopefully
13
      they'll indicate that, you know, if somebody has -- I don't
14
      have the list of all of these jurors, and I haven't gone
15
      through them like I suppose you have, so I suspect I'll ask
16
      the question to the panel. Anybody who says yes, I'm going to
17
      ask is it on your supplemental questionnaire? If it is, I'll
18
      have them sit down at that point. Those who haven't indicated
19
      it on the questionnaire, I'll ask just enough to get specific.
20
              But then with respect to these questions, do you feel
21
      that we need to conduct individual voir dire on some of these
22
     people or --
23
              MR. MOSKOW:
                           It may --
24
              THE COURT: -- all of them or --
25
              MR. MOSKOW: Your Honor, I believe it may be
```

appropriate. We believe it may be appropriate on individual cases to inquire perhaps either at side bar or outside the presence of the other jurors.

MS. JONES: We agree with that, Your Honor.

THE COURT: So here's what we'll do.

As I've indicated, we have the questionnaires. So whether it's somebody with new information or somebody with a questionnaire response, we'll just know who they are. And then, once I've gone through all of the questions, we'll start with Juror No. 1 -- I think I may have told you this has been my practice for the last few years.

We will just start with Juror No. 1 in the conference room, and I'll find out what inquiry you want to make of that juror, and we'll bring them in and do it. Then we will go to No. 2, 3, 4, 5, just down the line, and that will include follow-up questions about any of the matters identified in the jury questionnaire.

Okay?

MR. MOSKOW: Thank you, Your Honor.

THE COURT: All right. Then the preliminary instructions, start with plaintiffs.

MR. MOSKOW: Thank you, Your Honor.

I think we have three -- no, it looks like we have two on this issue as well -- or, no, three on this issue. So let me start with paragraph A5a.

```
1
              We would just ask for two changes in this paragraph.
 2
      First, plaintiffs make, not makes.
 3
              THE COURT:
                          Okay.
 4
              MR. MOSKOW: And in the second sentence, we would seek
 5
      to substitute the word need for must. So it will read, you
      need not automatically reach, as opposed to you must not.
 6
 7
              THE COURT: All right. I'll do that.
 8
              MR. MOSKOW: Thank you, Your Honor.
 9
              With regard to the section on compliance with safety
10
      standards, that is I believe on page 6 of your --
11
              THE COURT: Okay.
              MR. MOSKOW: Let me just -- just give me one second,
12
13
      Your Honor. I'm sorry.
14
              THE COURT: Page 8 of mine, the section compliance
      with safety standards?
15
              MR. MOSKOW: Yes, Your Honor.
16
17
              THE COURT: All right.
18
              MR. MOSKOW: So the plaintiffs' concern is essentially
      with the last sentence, which repeats and restates what is
19
20
      part of the pattern charge, but does so in a way that we think
21
      is a statement beyond that which the law provides.
22
              So we would either seek a striking of the last
23
      sentence, or it be edited to read as follows:
24
      compliance with appropriate regulations is competent evidence
25
      that BI exercised due care in the development and marketing of
```

```
1
      Pradaxa, it is not conclusive on that issue, and you should
 2
      consider all of the evidence before reaching your conclusion.
 3
              MS. JONES: Your Honor, we are satisfied with the
 4
      Court's instruction as written on compliance with safety
                  That final sentence is drawn verbatim from the
 5
      J.C. by and through Michelle C. versus Pfizer case, which is
 6
 7
      240 West Virginia 571.
 8
              Item 3 in the syllabus by the court reads: Compliance
 9
      with the appropriate regulations is competent evidence of due
10
      care. That is line for line what the law actually provides
11
      for, so we don't think a qualification or adjustment is
12
      necessary.
13
              THE COURT: All right. I'm going to leave it as it is
      for now. We'll make note of that. I might and probably will
14
      revisit that when we get to final instructions.
15
16
              MR. MOSKOW: Thank you, Your Honor.
17
              THE COURT: All right. Is that it?
18
              MR. MOSKOW: No, we have one last change, Your
19
      Honor --
20
              THE COURT: Okay.
21
              MR. MOSKOW: -- or request, I should say.
22
              This regards to conduct as jurors, No. 6 on page 9.
23
              THE COURT: Okay.
24
              MR. MOSKOW: At the risk of incurring the Court's
25
      wrath, because it's clear that you have a desire that the jury
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not take notes, the plaintiffs believe, given the substance matter that is going to be discussed and the length of the trial, it would be appropriate for the jurors to be able to take notes, at least during the evidence portion of the case if not during opening and closing.

THE COURT: All right. What do you say to that?

MS. JONES: We agree with that, Your Honor.

THE COURT: All right. This is just the standard language.

I'll tell you that I generally don't like to have the jurors try to take notes, but I think this trial falls within the exception because of the length and nature of it. So what I will do is rewrite this and make perhaps at least two or three points.

One will be that I will allow any juror who wants to take notes to do so. I will say don't feel obligated to take notes. It's a question of whether it is your preference and makes it easier for you to follow everything. And then some form of warning to the effect that your notes should be just for you, and other jurors shouldn't rely upon your notes, something to that effect.

So we'll change the language a little bit. I'll try to make sure you see that -- I will make sure you see that before we do it in the morning. But with that, we'll let jurors take notes if they so desire.

And the simplest way for us to do that is we will just get a bunch of legal pads and pens and make them available to the jurors, and we'll see what the jurors do with them.

I can't remember if you all talked about doing -- you talked about doing final exhibit notebooks at the conclusion, but you don't intend to do notebooks during the trial; is that right?

MR. MOSKOW: Your Honor, what we'll do is we'll publish exhibits as they're entered into evidence. I can speak for the live witnesses that the plaintiffs will put on. We will actually have notebooks for the witness, the Court and opposing counsel so that there isn't a lot of running around the courtroom with paper exhibits, but they will not go to the jury.

And what has seemed to work for the parties so far is that, you know, before closing argument, those agreed upon, the final list of exhibits, those are put numerically in order into binders, and those are available for the Court and the jury.

THE COURT: All right. Very good.

All right. That's all of the objections, then --

MR. MOSKOW: It is, Your Honor. Thank you for your

23 consideration.

THE COURT: All right. Let's start with your objections.

MS. JONES: Thank you, Your Honor. I guess we -- and we did raise this with plaintiffs' counsel over the course of the weekend.

We had a concern, and I suppose a more direct way of saying it would be we have an objection to the level of detail that is currently included in the instructions in terms of laying out all of the elements of the claims for each of the claims that exist. And I understand that this may well be the Court's practice, but if I may, I'll just kind of explain what our concerns are in this particular case with that approach.

The first is we expect that we will be making a motion at the close of the plaintiffs' case for a directed verdict, and we have some concerns about having a preliminary instruction to the jury that goes through in a fair amount of detail the elements for each of the claims when there is a possibility -- and obviously we can't predict this, but -- a possibility that all of those claims will not survive a motion at the close of plaintiffs' case. That's one.

The second concern is really that some of the elements that are laid out we think probably would be better explained to the jury once the evidence has actually come in. And the best example that I can point to is in the warranty claims, there are certain instructions related to what the warranty or the representation was that was made. I don't know that we have a clear sense at the front end of exactly what the

evidence will be on that. I think as the instructions are currently written, it suggests that the company made a representation about the medicine being safe, which in a prescription medicine case, it's a little bit in a posit just because of the nature of prescription medicines.

So that's just a threshold, more of a global concern that we have about the instructions as they're written.

What we had suggested to plaintiffs' counsel over the weekend was a possible general statement of the case. We certainly recognize the need to give the jury some sense of what the facts will be. We certainly have no objection even to laying out in a general way what the claims are that exist at this point in the case, but we have some concerns about the level of detail at which they are outlined in the instructions.

To the extent that the Court is inclined to proceed on this basis, then we have some more granular issues that we wanted to raise, but I wanted to put that issue in front of the Court.

THE COURT: Well, a fair matter for discussion. What is plaintiffs' response to that?

MR. MOSKOW: So, Your Honor, I think the way you stated that was absolutely correct, it was a fair matter for discussion. And we said, when they brought it up, why don't you put in writing what you're thinking. We looked at it, and

we looked at what you had done, and I think maybe we came to the same conclusion that the Court has.

That given the nature of this trial, given the amount of information that is going to be provided to the jury, that giving them a road map as to why this information is relevant or why they should be paying attention to particular things will be helpful. And I think that's particularly true given the number of claims here, that they have some understanding of exactly what they're here for.

THE COURT: Well, I struggled with this.

I always tell lawyers that I prefer that the preliminary instruction be brief and just provide the basic context of everything for the jury. But when you start looking at a case like this, the nature and number of the claims, unless plaintiff is willing to agree to either delete the references to each of the different claims or summarize them in some different way, I think I have to state -- identify each claim and the elements of that claim. And if there are things we can take out, excise to reduce this, that would be great.

I'm really worried that this is just going to go right over top of the jury, but I don't know that there is any alternative at this point unless the parties come to some type of agreement.

MR. MOSKOW: Your Honor, and maybe this would have

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been helpful for me to say when I was standing up originally.

If I had turned the microphone on, that might have been helpful as well.
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But we anticipate that the first several witnesses will be by videotape, so it will be, we think, particularly helpful in that context for the jury to hear what is going to come and then see the video.

THE COURT: Yeah.

Well, in any event, I think I'm going to have to deny your general objection. I think that the Court has to instruct, even in preliminary instructions, as to each of the claims, and so I don't see any shortcut to that other than if somehow the parties agree. So I guess we're going to have to get into the detail somewhat.

MS. JONES: Okay. Understood, Your Honor.

We just wanted to make sure we noted that --

THE COURT: Sure.

MS. JONES: -- for purposes of the record.

How would you like us to proceed? Because we've sent some red-line changes to plaintiffs' counsel. I'm happy to walk through those. They're not incredibly detailed, but there are several.

Would you like me to just go through these or submit them --

THE COURT: I guess, first --

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1
              MS. JONES: -- for the docket?
 2
              THE COURT: -- I'd like to see the extent to which
 3
      there is agreement.
 4
              If the plaintiffs disagree with your recommended
 5
      changes, then we'll just have to go through them page by page
 6
      or section by section, which is fine with me.
 7
              MS. JONES: Do you all have a copy of what we sent
 8
      yesterday?
 9
              MR. MOSKOW: I have it, Your Honor.
10
              Your Honor, plaintiffs have a general objection to the
11
      changes. We might be able to wordsmith them as we go through
12
      them with the Court, but --
13
              THE COURT: All right.
14
              MR. MOSKOW: -- there are a number of things that we
      just don't think --
15
16
              THE COURT: Then we'll just have to go through them.
17
      And as far as I'm concerned, you know, just start with the
      first page, and we'll --
18
19
              MS. JONES: Okay.
20
              THE COURT: -- see where that leads us.
21
              MS. JONES: That sounds good.
22
              Okay. The first section, A, General Instructions, we
23
      have no issues there.
24
              Section B, obviously subject to our objection earlier,
25
     we have no issue with that brief little introduction.
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70
              As to the section on plaintiffs' causes of action --
 1
 2
              MR. MOSKOW: Excuse me.
 3
              MS. JONES: Yes?
 4
              MR. MOSKOW: Would it be helpful to give the Court a
 5
      copy of it, and then -- we're okay if you want to provide --
 6
              THE COURT: If you've got a copy --
 7
                          I have a copy of the red line, if that
              MS. JONES:
 8
      would be helpful to Your Honor.
 9
              THE COURT: Do you actually have two copies?
10
              MS. JONES:
                          Yes, I do.
11
                          Give one to Blake.
              THE COURT:
12
              MS. JONES: May I approach, Your Honor?
13
              THE COURT:
                          Yes, you may.
14
              THE CLERK:
                          Thanks.
15
          (Counsel conferring.)
16
              MS. JONES: So I think we're on page 3, Your Honor,
17
      where we didn't have any changes as you can see.
18
              THE COURT: Okay.
19
                          On page 4, the first substantive change is
              MS. JONES:
20
      in the third element regarding proximate cause, where it reads
21
      that Pradaxa's defective warnings were a proximate cause of
22
      Betty Knight's injury.
23
              We have proposed that it also include the clause,
24
      including her death. Given the claims in the case, that would
25
     be consistent with what appears on page 6.
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1
              THE COURT:
                          It makes sense to me, where it's a
 2
      wrongful death claim as well as an injury claim.
 3
              MR. MOSKOW: Our concern, Your Honor, is that it
 4
      appears in this case to be all inclusive as opposed to an
 5
      either/or, which is consistent with the rest of -- that's
 6
      where I was saying this is the type of thing we could
 7
      wordsmith --
 8
              THE COURT: Well, I mean, it says the warnings were a
 9
      proximate cause of injury, including death, so I'm going to
10
      add the language that they are requesting.
11
              MR. MOSKOW: That's fine, Your Honor.
              THE COURT: Okay.
12
13
                          Your Honor, that would address our next
              MS. JONES:
14
      edit, which is at the bottom --
15
              THE COURT: I think it's the same, then.
16
              MS. JONES: Yes.
17
              On page 5, you'll see in our red line that we
      essentially outlined in a little more detail some of the
18
19
      elements that we believe are required to be proved in a
20
      failure to warn case under the causation prong.
21
              I'm not sure if plaintiffs have specific objections to
      these that we should talk about or -- or if the Court has a
22
23
      reaction.
24
              THE COURT: Well, what does plaintiffs say about this?
25
              MR. MOSKOW: A couple of things.
```

First of all, Your Honor, this goes down that slippery slope that we just started. So it takes out the word injury altogether, and now it's just talking about her death, so we have a concern about that.

Second of all, and maybe I'm overstating this, but I think part of what the Court was trying to do here was to restate complicated legal principles in plain language to people who are literally learning about this for the first time. And I think the use of the language, you know, the warning would have made a difference is essentially what we need to prove in terms of causation here.

It may be appropriate at the end of the case to provide more detail as to that issue, but what we're trying to do here is get the jury in place.

THE COURT: I agree with the plaintiffs. I'm going to deny your request with regard to these sections.

I guess the way you've divided these up, you've got a vertical line on the side that kind of separates --

MS. JONES: Yeah.

THE COURT: -- the objections.

MS. JONES: The vertical line on the side I think just indicates where there's a change.

THE COURT: Well, in any event, I do think that the Court's original language is sufficient for preliminary instruction.

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1
              And then just as an incidental note, in that last
 2
      sentence, it would be redundant to include the including her
 3
      death addition there. Because if I did your language, it
 4
      would say if Pradaxa didn't cause death, or if a warning would
 5
      have prevented injuries, including her death -- well, maybe
 6
      it's not the same.
 7
              But, in either event --
 8
              MS. JONES: So just a question, Your Honor?
 9
              THE COURT: All right. Here's what I'll do just to
      make it simple.
10
11
              MS. JONES: Okay.
12
              THE COURT: I will add the including her death
13
      language --
              MS. JONES: Your original instruction --
14
15
              THE COURT:
                          -- to be consistent with the evidence, but
16
      deny the balance.
17
              MS. JONES: And just so I say it to be clear, Your
      Honor, we have sufficiently preserved our objections for
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19
      purposes of arguing instructions at the close of the evidence,
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      I assume?
2.1
              THE COURT: Absolutely.
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              MS. JONES: Okay. Thank you, Your Honor.
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              THE COURT:
                          Okay.
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              MS. JONES: I think that takes us to page 6 and the
25
      warranty instruction, and this was the point that I mentioned
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earlier.

You can see we have proposed to eliminate the phrase represented that Betty Knight could safely use Pradaxa, and proposed to replace that with made a statement of fact about Pradaxa. Excuse that extra A in the word Pradaxa there.

And we made a corresponding change in the second element of that claim as well as including the including her death clause at the end of the fifth element, which carries over to page 7.

MR. MOSKOW: Your Honor, we like the way it was written. We don't have a huge objection to these changes, but we think as written it was appropriate.

MS. JONES: And our only view, Your Honor, was that it would probably be better to state that more generically at this stage in terms of what the alleged representation was.

And when we get to the closing instructions, then maybe it would be an appropriate time to give further detail on that point.

THE COURT: Well, I do think these are all subject to being revisited. And as long as they're accurate, even though more general, then the final instructions are likely to be -- I'm satisfied with them.

So I'm going to deny the first request -- or first objection you have under the express warranty matters. But then I'll add the including her death language on the next

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1
      page to be consistent. And likewise in the implied warranty,
 2
     No. 5.
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              MS. JONES:
                          Thank you, Your Honor.
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              MR. MOSKOW: Thank you, Your Honor.
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              MS. JONES: The only other issue we had on implied
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      warranty was with respect to the third element that is
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      described here concerning promises or affirmations of fact.
 8
      And I think the original phrasing was made on the container
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      label or the Medication Guide.
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              We weren't clear on what exactly container was a
11
      reference to, and I'm not sure, as a legal matter, that BI is
      responsible for --
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13
              MR. MOSKOW: We have no issue with that, and we'll
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      note our objection for the record, but understand that
      including death will be included in paragraph 5.
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              THE COURT: All right. I'll adopt the change proposed
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      by the defendant.
                                 Thank you, Your Honor.
18
                          Okay.
19
              Your Honor, subject to obviously our earlier objection
      on the detail point, those are all the issues that we have
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21
      with respect to the preliminary instructions.
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              THE COURT: All right.
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              MS. JONES:
                          Thank you for hearing us on that.
24
              THE COURT: And then on the -- and we'll alter the
25
      discussion about note-taking.
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MS. JONES: Yes, Your Honor.

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THE COURT: All right. So does that resolve all of either side's objections to voir dire or preliminary instructions?

MR. MOSKOW: For the plaintiff, it does, Your Honor. Thank you.

MS. JONES: Also for the defense. Thank you, Your Honor.

THE COURT: All right. The next note I had on my list was any other matters under the joint proposed amended integrated pretrial order. Is there anything else that we need TO take up from that?

MS. JONES: I don't think so, Your Honor. I think we have agreement that we will have an hour per side for openings. I recall you saying you wanted us to try to achieve agreement on that, and I believe that we have.

THE COURT: All right. And then I assume each of you are going to use some type of presentation. So have you been able to vet your opponent's presentations, whatever you're going to use, whether it's a power point or actual exhibits or whatever?

MS. JONES: We have a schedule in place as part of the PTO where we will exchange slide very early in the morning, and we'll obviously talk about any issues that we have. If there is anything that needs the Court's attention, we'll

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bring that to your attention.
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THE COURT: All right. So at this point, there are no other issues that the parties have identified that the Court need address today?

MR. MOSKOW: May I have one moment, Your Honor?

THE COURT: Yes.

MR. CHILDERS: Your Honor, per your instruction, I went and found some information about Dr. Connolly that I'm happy to share with Your Honor.

THE COURT: Great.

MR. CHILDERS: First is the paper itself, once it was published, that we -- may I approach, Your Honor?

THE COURT: You may.

MR. CHILDERS: Your Honor, this is the paper itself.

It shows that Dr. Connolly received -- is a consultant -- received consulting fees and other honoraria from Boehringer.

There is additional information in the deposition of Jeffrey Friedman where he was asked specifically how much did Dr. Connolly and the rest of his group, which is the PHRI, is what they call them, get paid to do the work that they did. And it was -- the answer was, it's probably, I would guess, in excess of 50 million dollars.

So I think we've clearly established he got paid a lot of money to do what he was doing by this company and,

therefore, I think he is an agent of the company for purposes of what we seek to do.

MS. JONES: Your Honor, may I respond to that briefly?

THE COURT: Yes.

MS. JONES: So this paper is the exposure response paper that you've obviously heard quite a lot about. And it is an entirely mundane thing that doctors, like Dr. Connolly, disclose when they are authors to this type of paper, I have a relationship with the company, I've been paid by the company at certain points. This is an entirely routine, entirely proper disclosure.

If every time an outside scientist made a disclosure like that, that person became an agent of the company for purposes of the hearsay rules, it would blow open the exception to the rule for party admissions.

The fact that Dr. Connolly may have received grants from the company and may have disclosed that in the appropriate course, as he was required to do by the journal, certainly does not turn him into an agent. And the fact he works for an institution that was part of a large clinical trial, which happens all the time, does not turn him into an agent of the company. What they're proposing would completely eliminate the boundaries on the party admission rules.

THE COURT: Okay. You want to reply?

MR. CHILDERS: Your Honor, he got paid fifty -- his

group, including him, got paid 50 million dollars to run this study for the company. He became an agent of theirs and then wrote this paper along with them, with their employees and the other folks at his institute. They got the 50 million dollars. I think that satisfies the issue of whether or not he was an agent for this purpose.

THE COURT: Well, I have to say looking at this, to me it's a little more ambiguous about whether he was being paid by BI for this work, and I'm not sure that the part that you've highlighted convinces me that that is the case.

It certainly would be appropriate for any author in a peer-reviewed article to identify any past as well as current connection with someone whose product is under the analysis.

What I'm interested in, and I don't know if you can answer this, but that bottom footnote, if that's what it is, starts off with the sentence from departments of clinical development, and then there is an asterisk.

And so does that asterisk refer to --

MS. JONES: It reflects --

THE COURT: -- connect the authors listed above to that asterisk?

MS. JONES: Yeah, so all these little figures here match up with the ones at the bottom. So that asterisk at the bottom matches up with Paul Reilly's name as well as Susan Wong's name. You'll see that later in the list of authors.

And then if you look at Dr. Connolly, he has a different indicator for his affiliation with Population Health Research Institute, McMaster University.

So those little symbols just indicate the affiliations of the authors.

THE COURT: Yeah, I don't think this is enough to convince me that Dr. Connolly was an agent of BI at the time he made these statements sufficiently that the statements could be attributed to BI.

So I've forgotten what the context was.

MS. JONES: I think that was our motion, Your Honor.

THE COURT: I think I was granting the defendant's objection.

Do you want to put this in the record as part of this --

MR. CHILDERS: Sure, Your Honor. And I would also just point out -- we've been trying to pull these up, and we haven't gotten them all.

Dr. Connolly also has specific service agreement contracts with BI during this entire time period, and I'm happy to provide those to Your Honor tomorrow. I just can't print them out here in the courthouse.

This guy is working for the company. Whether he's at another institute doing it or not, he's working for the company.

THE COURT: Well, if you've got something that you think materially changes the application of my analysis, I'm happy to look at it and consider it. I'm skeptical, but I'll let you present whatever you come across.

So Plaintiffs' Exhibit 3247 -- boy, that's alarming. We haven't even started trial, and we are already on Exhibit 3247. In any event, it's made a part of the record of this pretrial or final settlement conference.

All right. Then is there anything else that you all have that you want to discuss before I get to some of these mundame matters?

MS. JONES: This may be a mundane matter, Your Honor.

Just for purposes of opening, is it acceptable to the Court if counsel -- obviously we are not going to be running around the well, but -- step away slightly from the podium to use a board? Is that okay?

THE COURT: Yes. And if you'd like, and I would suggest if you are going to be up there for an hour, we can rotate that podium.

MS. JONES: Okay. Terrific.

THE COURT: So just remind us in the morning. It takes a couple of people to turn it kind of carefully. There are plug-ins underneath it, so you have just got to be careful that we don't accidentally unplug something or put counsel in a position where they're going to be standing next to a plug

they might accidentally hit or kick or something.

MS. JONES: Thank you, Your Honor.

THE COURT: Yes. You can use that.

I will remind you that because the acoustics are not very good in here, my court reporter has to depend upon the microphone system. So when you step away, make sure that you speak loud. I think you all are experienced trial lawyers, so that is probably a natural for you.

Unfortunately, whether it's lack of experience or whatever, many lawyers get here in the courtroom and talk so quietly even with the jury that it is hard for us to hear, and there is just no way my court reporter can hear that when she's trying to listen through the system.

So that reminds me of a couple of points.

One, we'll probably have numerous bench conferences. When we do that, I like the plaintiffs to come on this side, the defense to come on the other side, so my court reporter can get here in the middle if she wants to.

She's got now a recording device, which is keyed to this bench microphone, and this bench microphone doesn't broadcast over the system, so she just hears that. So if this works, she may not have to relocate, which will be great.

Because if she has to move in the middle to hear you folks, it becomes really difficult.

And so we're going to try to use the recorder, but it

will be difficult for her to keep up with it on a real-time basis if she has to depend upon listening to the recorder. So we'll just see how it goes. We are going to play with this thing later today, and hopefully I can tell you tomorrow that when we have bench conferences, she won't have to relocate and move to the middle, and you can crowd up here with me. And I've got the courtroom microphone here, which I'll just turn off.

Also, we do have the white noise feature, and we'll use that probably every time if I can remember to direct somebody to turn it on.

Also, you all have asked for daily transcripts or at least one side has, I guess.

Are both sides doing that?

MR. MOSKOW: I believe the defense has, Your Honor. The plaintiff hasn't.

THE COURT: So we've got one of our colleagues in the Charleston division who is going to be here. She and our court reporter have worked out a schedule. They're each going to do quarters each day and alternate so we can work on this.

I think I can speak for both the court reporters, they're very nervous about being asked to do a read back of a question or an answer if we get into that situation with a witness where, because of an objection or something or for any other reason, counsel says can you read that back to me. So

try to minimize that. We'll depend upon you to try to restate those things, and don't expect that if you've lost your train of thought that we're going to be able to necessarily come to your rescue with a read back.

I've got the realtime. I don't mind summarizing things. But, you know, I just want to make clear that we're probably going to ask that you not ask the court reporters to literally read back a question or an answer.

And then with regard to the daily transcripts, I don't know that I've actually had a trial where one side has asked for that. I don't remember offhand. I don't know what you expect to do with that daily transcript, if anything, other than for your own purposes.

Do you purport that that becomes an official transcript, and that you could use that -- obviously not for the jury, I guess, but be quoting from that as an official transcript during questioning of other witnesses or argument with the Court? I don't know what you plan to do with it.

MS. JONES: I can tell Your Honor, just based on our experience in the earlier trials, that usually part of it is just for our internal purposes for preparing for other witnesses, preparing for closing.

THE COURT: Right.

MS. JONES: To some extent, we probably have relied on daily transcripts for purposes of arguments that have come up

during the course of the trial. I don't think we've done that extensively or excessively, but I think that has been the case to some extent.

I'm not sure that there have been many, if any, examples of places where we've used a daily trial transcript with a witness on the stand, and I'm not readily coming up with something where I would expect that to happen. But those are the general buckets of how we've used them in the past.

THE COURT: Well, I'm going to talk with my court reporters this afternoon and see how they view these daily transcripts. I have always presumed that because it is such a quick turnaround, that they are not considered official transcripts. They're not filed and docketed by the Court as the official transcript. And if that's the case, then I'm probably going to be very hesitant to let you read from a daily transcript in questioning a witness.

I guess, you know, if it's argument of motions and things like that or issues with the Court, I guess I don't see the official -- or the unofficial transcript that you have as being much different from somebody's notes or best memory, and so I don't know that I have a problem with that.

Mostly I'm hesitant to make the jury aware of these daily transcripts because, as a matter of routine, I instruct jurors that they should not expect to have a transcript of any of the witness testimony for the purposes of their

deliberation. Because obviously in the vast majority of cases, we don't have any kind of transcript, and certainly not an official transcript, and so I don't know that there's any reason to believe that this would be any different.

But if you think that there is a different or more complete use of the daily transcript, let the plaintiffs and the Court and the court reporter know that before we get into an issue. Okay?

MS. JONES: We're happy to be guided by whatever Your Honor prefers.

The one example that did come to mind for me in terms of witnesses that we sometimes have given the daily transcript to is an expert who we are calling later, and we might ask the person, when we present that witness, did you have a chance to review the testimony of so and so? Beyond that, we don't use the transcripts for any purpose during examination. But in the interest of just giving Your Honor a sense of how it might have come up in the past, that is one example.

THE COURT: Well, in the instance you've identified with an expert, then, you would purport to consider giving an expert a daily transcript of a prior witness's testimony when they were not present to hear that testimony?

MS. JONES: Correct. For example, with experts who just aren't able to be here every day of the trial who obviously would be entitled to be in the courtroom while other

folks are testifying. I think it's mostly come up with physician experts.

THE COURT: You all have a concern about that?

MR. CHILDERS: The only concern I would have, Your

Honor, is if they're quoting it or something along those

lines. The jury will remember whatever they remember from the testimony, but I don't mind them looking at it.

THE COURT: All right. Well, we'll see if we encounter that. Obviously I don't want the jury to be misled by the availability of a daily transcript, and it might be a little bit problematic if I let you use those openly and quote from them or have a witness quote from them and then at the end of the evidence tell the jury they can't see these transcripts. So that would be a concern.

All right. Is there anything else that you all have identified that we need to take up?

MR. CHILDERS: Your Honor, may I just ask one question about procedure?

In terms of moving the transcripts from the video plays and the exhibits that are referenced in them, those will be done by agreement of the parties. Is it your preference to do that in front of the jury or outside the presence of the jury? Because they are transcripts, and you don't want to talk about transcripts.

THE COURT: My preference would be to do that outside

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      the presence of the jury. The jury doesn't need to hear that
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      or be delayed with whatever they're doing.
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              MR. MOSKOW: Thank you, Your Honor.
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              THE COURT: All right.
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              MR. CHILDERS:
                             Just so I'm prepared for tomorrow, how
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      are we going to sort of logistically do this with the jury?
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      Are they coming in the back here?
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              THE COURT: Here's how we do it.
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              So I think --
          (Off-the-record discussion with courtroom deputy.)
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              THE COURT: So we have between 30 and 35 people.
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      will show up downstairs. When they come in downstairs, they
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      will be checked off by the clerk's office. The clerk
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      downstairs will randomly by computer assign a number to each
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      juror, 1 through -- I guess we will have 32 since we're
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      excusing those three. I think that's the right number.
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              What we tell the clerk's office is how many we want to
      show up, so usually they'll ask -- they'll have a few more
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      than that because almost invariably we have somebody who
      either is really late and we don't want to wait or, for
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21
      whatever reason, just didn't get the word. That does happen
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      legitimately unfortunately sometimes.
23
              In any event, they'll show up. They'll each be given
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      a number. They will have a sticker with that number that will
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be marked. And then when they're all assembled and ready to

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go, the clerk's office will notify us. We'll be waiting for them. They're usually pretty efficient. So pretty close to 9:00 or maybe 9:10, we should have them all down in the clerk's office.

The clerk will then bring us, first, that numerical list that will have the juror's name, address, and I think maybe it lists their occupation. And then on the right side is a column where our form has a blank space for different objections, for cause, plaintiffs' peremptory, defendant's peremptory, and you'll be able to use it for that. So that list will accompany the jury up here.

So when we're told they are coming up, I will let you know and expect you to realize that we've got jurors filtering into the courtroom. It takes them a few minutes to get up here. Some people will take the steps and be here quickly. Some people will take the elevator. You know, it seems like they trickle in.

When they come in, we'll have them seated in that numerical order in the jury box and in the bench seats out there. You'll have that list that shows their name, their new number, and have a space for you to mark any excused or removal of that juror from the list, and then we'll get started.

As I told you, I think we'll end up probably spending a good part of the morning in the conference room doing this

individually, and then we'll see where we go. It's six to twelve people. I think we will probably have a jury of eight or nine. And honestly whether it's even an number or an odd number depends upon how many we have left when we start peremptory challenges. We will just divide those up evenly and let the parties go to it.

Usually when I do these peremptory challenges, because you will get more than one or two, I'll see how many we have. If each side is going to have -- each side could have as many as eight or ten peremptory challenges. Whatever that number is, if it is a number like that, I'll tell you at the time we're going to do this in two or three -- well, in three rounds. So if you've got eight challenges, you might have to do three, three and two; you might have to do three, three and two. It will be same, whatever it is. But we will do that in two or three rounds, probably three rounds instead of one at a time. It just goes faster.

MR. LEWIS: Is that done in open court, Your Honor?

THE COURT: Yes.

MR. LEWIS: Okay.

THE COURT: Once we finish all of the voir dire -- I assume we'll be in there when we finish -- we will come out here. We will formally convene. I'll tell the jurors that we have completed the voir dire. Now the parties are going to do their peremptory challenges.

At that point, I will tell the jurors that I'm going to excuse the parties and let you leave, go to a conference room or somewhere else to huddle up separately and talk about what your strategy is. I will give you maybe five or ten minutes to do that, and then bring you back in here, and we'll start those peremptory challenges and exchanges.

I tell the jurors generally that when they are waiting, that while we're technically still formally in court, that they can stand up, move around a little bit. They can talk to each other as long as they are not talking about anything about the case or the process, go to the restrooms, which are in here, if they need to. But I generally try to keep them at or around their chair, partly so you can put a face with a name. We'll give you a few minutes between the close of all that voir dire and the start of the exchange of peremptory challenges.

MR. CHILDERS: Your Honor, the challenges, will they be, Juror No. 1, does either side have a challenge or --

THE COURT: No.

MR. CHILDERS: We can pick any --

THE COURT: You can pick anyone.

We'll have up to 32 people. And if nobody is released for cause, then we'll probably have an eight-person jury, and that's 24 that will have to be struck. I'll give each side 12, and you'll take turns marking your challenges off of that

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      whole list of 32 people.
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              MR. CHILDERS: Sorry. I misunderstood.
              I thought there were three different groups --
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              THE COURT: Well, not three different groups.
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              You're going to get to do three series of challenges.
      So if you've got 12 strikes, I'm going to tell you do four in
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 7
      your first round, and then they do their four, do four in your
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      next, like that. That's all I meant by that.
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              MR. CHILDERS: Understood.
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              THE COURT: But it can be anybody on that list.
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              MR. CHILDERS: Okay. Thank you, Your Honor.
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              MR. MOSKOW: May I just ask, will for cause challenges
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      be done on the record or --
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              THE COURT:
                          Yes.
              MR. MOSKOW:
                          Thank you.
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              THE COURT: What I prefer to do is when we're doing
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      this individual voir dire, and I'm sure we'll do individual
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      voir dire of probably anybody that either side is going to
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      want to strike for cause, as soon as they walk out of the room
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      is your time to -- and I'll point that out. That's when
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      either side or both can speak up about a challenge for cause.
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              I don't tell the jurors they're excused until we deal
23
      with all of them.
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              MR. MOSKOW: That's fair.
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              THE COURT:
                          I don't want there to be a mad rush to the
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doors. So I just tell even jurors that -- I might say -- if somebody has got some obvious logistical problem that is going to require me to excuse them, and you all agree, and you've discussed that, I'll tell them, well, you're going to stay seated until we excuse everybody together just so we don't start having people dribble out one at a time.

And the only reason I do that is I've found in the past, if somebody gets excused like that, then other people start saying I've got something, too. So, anyway, that is generally how we handle it.

I guess you have already figured out where you can -the room you can use for staging for when it's your case.

Any different estimate about how long it's going to take for you to put on your evidence?

MR. CHILDERS: I still think we'll be done before three weeks, Your Honor, with the whole trial, like I told Your Honor the last time we were here.

THE COURT: Right.

MR. CHILDERS: Whether it's two weeks or two weeks and change, I couldn't --

THE COURT: Okay. Same for you folks?

MS. JONES: Same for us, Your Honor.

THE COURT: All right. How many of you are going to be here? How many lawyers are you going to have here at counsel table? Everybody, everybody who is here now?

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              MS. JONES: No, the whole gang will not be here every
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      day. It will be Mr. Lewis and Ms. Callas and myself at
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      counsel table.
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              THE COURT: Okay.
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              MR. CHILDERS: Two of us, Your Honor. And Mr. Knight
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      will be here most days, and Ms. Stevens will also be here.
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              THE COURT: Okay.
              MR. CHILDERS: Then Mr. Abney may -- if he is going to
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 9
      handle a witness, we'll swap out.
              THE COURT: All right. Is there anything else?
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11
              If not, be back here at 8:30 in the morning, and we
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      should be good to go.
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              MS. JONES: Okay.
14
              THE COURT: See you in the morning.
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              MR. CHILDERS: Thank you, Your Honor.
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              MR. MOSKOW: Thank you, Your Honor.
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              MS. JONES: Thank you, Your Honor.
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              MR. LEWIS: Thank you, Your Honor.
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                (Proceedings were adjourned at 12:06 p.m.)
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1	CERTIFICATION:
2	I, Kathy L. Swinhart, CSR, certify that the
3	foregoing is a correct transcript from the record of
4	proceedings in the above-entitled matter as reported on
5	October 1, 2018.
6	
7	
8	October 10, 2018 DATE
9	DAIE
10	/s/ Kathy L. Swinhart KATHY L. SWINHART, CSR
11	RAINI L. SWINNARI, CSR
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